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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	09/614,790
		Filing Date	July 12, 2000
		First Named Inventor	Kleyne, Sharon
		Group Art Unit	1617
		Examiner Name	Michael Willis
Total Number of Pages in this Submission	28	Attorney Docket Number	HME/7982.001

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#### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

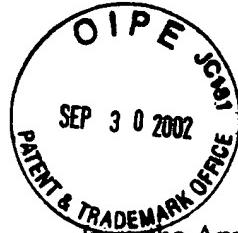
Firm or Individual Name	Howard M. Eisenberg 1600 ODS Tower, 601 SW Second Ave Portland, OR 97204-3157
Signature	
Date	September 24, 2002

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Signature		Date	September 24, 2002





Atty Doc. No. HME/7982.001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT APPLICATION EXAMINING OPERATIONS**

In re the Application of  
Sharon F. Kleyne

Serial No. 09/614,790

Filed: July 12, 2000

For a Patent for  
METHOD AND KIT FOR MOISTURIZING  
THE SURFACE OF THE EYE

: Group Art Unit: 1617  
: Examiner: Michael Willis  
: Tel. No. (703) 305-1679

: Date: September 24, 2002

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**TRANSMITTAL OF APPEAL BRIEF - PATENT APPLICATION  
UNDER 37 C.F.R. §1.192**

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir,

Transmitted herewith, in triplicate, is the Appeal Brief in this application, with respect to the Notice of Appeal Filed on July 25, 2002. Pursuant to 37 C.F.R. §1.17(c), a check for \$160, the small entity fee for filing the Appeal Brief, is enclosed herewith.

Respectfully submitted,

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**CERTIFICATE OF MAILING**

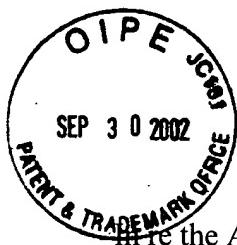
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Dated: Sept 24, 2002

Howard M. Eisenberg

1 of 3

Atty Doc. No. HME/7982.001



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT APPLICATION EXAMINING OPERATIONS

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In re the Application of : Group Art Unit: 1617  
Sharon F. Kleyne  
  
Serial No. 09/614,790 : Examiner: Michael Willis  
  
Filed: July 12, 2000 : Tel. No. (703) 305-1679  
  
For a Patent for : Date: September 24, 2002  
METHOD AND KIT FOR MOISTURIZING  
THE SURFACE OF THE EYE

**APPELLANT'S BRIEF UNDER 37 C.F.R. §1.192**

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir,

This brief is in furtherance of the Notice of Appeal, filed on July 25, 2002. The fees required under 37 C.F.R. §1.17 are dealt with in the accompanying Transmittal of Appeal Brief. This brief is transmitted in triplicate, as required under 37 C.F.R. §1.192(a).

This brief contains the following items under the following headings, and in the order set forth below, according to 37 C.F.R. §1.192(c), each item beginning on a separate sheet.

- I. Real Party in Interest
- II. Related Appeals and Interferences
- III. Status of Claims
- IV. Status of Amendments
- V. Summary of Invention

VI. Issues

VII. Grouping of Claims

VIII. Argument - Rejections under 35 U.S.C. §103(a) under 37 C.F.R. §1.192(c)(8)(iv)

IX. Appendix of Claims Involved in the Appeal

The final page of this brief bears the signature of the Attorney for Appellant and a Certificate of Mailing.

## I. Real Party in Interest

The real party in interest in this appeal is the party named in the caption of this brief.

## II. Related Appeals and Interferences

With respect to other appeals and/or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences.

### III. Status of Claims

The status of the claims in this application is as follows.

Claims in the application are 1 to 82. Claims 1 to 74 have been cancelled. Claims 75 to 82 are pending and have been twice rejected. The claims on appeal are claims 75 to 82.

IV. Status of Amendments

No Amendments have been filed subsequent to the final rejection dated May 1, 2002.

## V. Summary of Invention

Appellant's invention comprises a method for moisturizing the eye. Appellant's method for moisturizing the eye is to administer to the surface of the eye an amount of an aqueous fluid that is less than that which will flood the eye. The amount of fluid administered according to the invention as claimed is 3 microliters or less. See, the specification, page 4, lines 11-16. The method of the invention is a significant advance over the prior art as it results in the rehydration of the aqueous layer of the tear film with the retention of the integrity of normal trilaminar structure of the tear film. See, the specification, page 4, lines 6 to 10, and page 10, line 12-17. This is in contrast to present day methods of moisturizing the eye in which a quantity of a hydrating fluid, typically in the form of a drop, a stream, or a jet of drops,, is administered to the surface of the eye, which quantity of water washes away the tear film and replaces it with the hydrating fluid. See, the specification, page 2, line 26, to page 3, line 2, and page 10, lines 5 to 11.

In a preferred embodiment of the invention, the aqueous fluid is administered as a mist. See, the specification, page 4, line 22. Application by a mist provides optimal hydration of the tear film and moisturization of the surface of the eye. See, the specification, page 4, lines 21-26. Application of the volume of fluid by a mist results in a sudden increase in moisture to the tear film. This is in contrast to a splash of fluid, which is obtained with a drop or with a jet or stream of fluid. The mist, in contrast to the splash, causes an increase in the water content of the tear film without disrupting the integrity of the tear film. See, the specification, page 5, lines 10-14.

It is preferred that the size of the droplets that are applied to the eye be within the range of 5 to 150 microns, such as less than 20 microns. See, the specification, page 6, lines 9-36.

Support for all limitations of the claims is contained in the above cited portions of the specification.

## VI. Issues

The issue is whether claims 75 to 82 are patentable or unpatentable under 35 U.S.C. §103 over the combined disclosures of Embleton et al. (WO 97/23177) in view of Laibovitz et al. (U.S. Patent No. 5,997,518).

## VII. Grouping of Claims

Claims 75 to 77 stand or fall together. Claim 78 stands or falls by itself. Claims 79 to 81 stand or fall together. Claim 82 stands or falls by itself.

Reasons for the above grouping of the claims is provided in the Argument under 37 C.F.R. §1.192(c)(8) that follows.

VIII. Argument - Rejections under 35 U.S.C. §103(a) under 37 C.F.R. §1.192(c)(8)(iv)

A. Arguments pertinent to all claims 75-82

1. The Examiner has improperly failed to consider the preamble as a limitation of the claims, and thus has failed to make a *prima facie* case for obviousness of the claims

It is axiomatic that a claim must be considered in its entirety. A large body of case law exists regarding the issue of whether the wording of the preamble to a claim is to be considered to be a limitation of the claim for purposes of patentability. The leading case on this issue is *Kropa v. Robie and Mahlman*, 88 U.S.P.Q. 47.8 (C.C.P.A. 1951).

In *Kropa*, the court held that the preamble is considered as a limitation if it is: "considered necessary to give life, meaning, and vitality to the claims or counts." Thus, the court held that the words in the preamble "An abrasive article" were to be considered a limitation because these words" are essential to point out the invention defined by the counts". *Id. at 481.*

In the present case, the preamble of claim 75, from which each of claims 76-82 depends, recites "A method for moisturizing the eye." These words of the preamble are essential to point out the invention defined by the claims.

The Examiner has rejected the present claims for obviousness over a combination of references, (referred to herein as Embleton and Laibovitz, respectively) each of which discloses an apparatus for delivering a controlled, small amount of fluid to the surface of the eye. The reasons why it is important to deliver a controlled, small amount of fluid to the eye is so that, when dispensing a medication, two bad results do not occur. The first bad result is that

delivering a medication in a large amount of fluid will result in flooding the eye with runoff onto the cheeks, which will cause some of the medication to be lost as tears. This results in wastage and an inability to determine what dosage of the medication was actually delivered to the surface of the eye. The second bad result, and the potentially more serious of the two, is that delivering a medication in a large amount of fluid to the eye with resultant flooding of the eye will cause some of the fluid, containing medication, to flow down the tear duct into the nasal passages from where it will be inhaled. This will cause some of the medication, intended for topical application to the eye, to systemically enter the body which can lead to serious side effects.

Neither Embleton nor Laibovitz disclose or suggest that the small amount of fluid that can be delivered by their apparatuses is sufficient to moisturize the surface of the eye. There is no suggestion in the prior art that volumes as small as less than 3 microliters as called for in claim 75 are suitable to moisturize the eye. There is further no suggestion in the prior art that volumes as small as less than about 2 microliters are suitable to moisturize the eye, as called for in claims 76 and 80. It is the present applicant who has discovered that, not only are such small volumes of fluid sufficient to moisturize the eye, but that such volumes are actually preferred over present day methods of moisturizing the eye, i.e. by eye drops, or by jets or streams of fluids such as delivered by the apparatuses of Embleton and Laibovitz.

The determination of obviousness under 35 U.S.C. §103 is whether the claimed invention, *as a whole*, is obvious. *Stratoflex, Inc. v. Aeroquip Corporation*, 218 U.S.P.Q. 871, 877 (Fed. Cir. 1983). Appellant submits that the Examiner has failed to make a *prima facie* case of obviousness because the prior art does not disclose or suggest the presently claimed method as a whole, that is including the words of the preamble, "for moisturizing the eye."

2. The Examiner has improperly disregarded the Declaration of Dr. Rachael Garrett Dr. Rachael Garrett, a clinical optometrist working at Oregon Health Sciences University, submitted on behalf of Appellant her FIRST DECLARATION OF DR. RACHAEL GARRETT in which Dr. Garrett rendered her opinion on the issue of how one skilled in the art would understand the disclosure of the Embleton reference on page 12 regarding "water". Dr. Garrett, who provided a long list of her publications and presentations with her Declaration, qualifies as an expert in the field of optometry.

Dr. Garrett stated in paragraph 5 of her Declaration that:

Therefore, it is my understanding that Embleton does not disclose the use of water, per se, as an artificial tear/dry eye therapy or comfort drop.

Rather, my understanding is that Embleton discloses artificial tear/dry eye therapies and comfort drops that are based upon saline, water or oil, and which include other ingredients that are necessarily present in these formulations.

Dr. Garrett further stated in paragraph 6 of her Declaration that:

It is my opinion that most eye care professionals, other than myself, would also understand the disclosure of Embleton as I have stated above.

Dr. Garrett's conclusions were not based solely on her speculation or opinion but was based in fact, as stated in paragraph 4 of her Declaration. This paragraph states that:

*Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects. These essential ingredients include (a) tonicity agents such as dextran 40 and 70,*

glycerin, potassium glycol, and sodium chloride, (b) viscosity increasing agents, such as carboxymethylcellulose, dextran 70, gelatin, glycerin, hydroxymethylcellulose, poloxamer 407, polysorbate 80, propylene glycol, polyvinyl alcohol, an polyvinylpyrrolidone, and (c) wetting agents, such as polysorbate 20 and 80, poloxamer 282, and tyloxapol. Additionally, these formulations usually, but not necessarily, contain (d) preservatives, such as benzalkonium chloride, cetylpyridinium, thimerosal, methyl/propyl paraben, sodium benzoate, sodium propionate, and sorbic acid, and (e) antioxidants, such as EDTA, sodium bisulfite, sodium metabisulfite, sodium thiosulfate, and thiourea. (emphasis in italics and underlining added)

Dr. Garrett's Declaration was further supported by evidence supplied by Appellant's attorney in an Amendment filed July 9, 2001. In that Amendment, as Exhibit 1, Appellant furnished several pages of the Physician's Desk Reference to show that artificial tears, irrigation fluids, eye washes, and comfort drops, contain ingredients other than water that are essential for their function.

Following the submission of this Declaration, which set forth stating facts and fact-based opinions to establish that one skilled in the art would understand the disclosure of Embleton to refer to water based therapies, the Examiner responded with evidence that is not pertinent to the issue addressed by the Declaration. The Examiner provided two U.S. patents, Ogura, U.S. Patent No. 5,307,095, and Scheiner, U.S. Patent No. 5,627,611, to show that "water is an art-recognized artificial tear/dry eye therapy."

Ogura discloses an apparatus for moistening the surface of the eye, which apparatus includes a pair of glasses, which preferably are enclosed goggles, and a liquid-containing member mounted on the inside of the goggles so as to reside in the space bounded by the goggles and the face of a wearer. The water in the liquid-containing member evaporates and increases the humidity of the air within the goggles, which air is in contact with the eyes of the wearer. Thus, the eyes are maintained in a high-humidity atmosphere and are constantly moisturized.

Ogura is not pertinent to artificial tears or any other episodic means of administering moisture to the eye. What Ogura discloses is evaporated water, that is water that is dissolved in the air and is in the form of a gas. Such a gas moisturizes the eye continuously, not episodically as does the application of artificial tears, which are in the form of a liquid.

Scheiner, although entitled "Artificial Tears", does not relate to artificial tears. Rather, like Ogura, Scheiner discloses increasing the humidity in the "dead space" between a pair of goggles and the face of a wearer by providing a chamber containing water mounted within the goggles. Like with the invention of Ogura, water from the chambers evaporates and the resultant high-humidity air is trapped within the goggles, thus keeping the air exposed to the eyes more moist than is the air outside of the goggles. Scheiner differentiates his invention from artificial tears, in column 1, lines 14-22, as artificial tears must be applied episodically and provide only temporary relief.

It is clear that the two patents relied upon by the Examiner to rebut the Declaration of Dr. Rachael Garrett, and her conclusion that the art recognizes that artificial tears necessarily contain ingredients other than water which are essential for their efficacy, do not in any way relate to artificial tears, comfort drops, or irrigation fluids.

Accordingly, Appellant submits that insufficient consideration was given to the Declaration of Dr. Rachael Garrett and that, with this Declaration, the Examiner should have found that the rejection of the claims over Embleton, either alone or in combination with Laibovitz, was overcome.

B. Arguments pertinent to all claims 79-82

1. The Examiner has improperly rejected Appellant's definition of the term "mist"

There are many cases that hold that a patentee may be his/her own lexicographer, that is that a patentee may assign a definition to a term even if such definition is contrary or inconsistent with the ordinary meaning of the word. See, for example, *Renishaw plc. v. Marposs Societa' per Azioni*, 48 U.S.P.Q.2d 1117, 1121-1122 (Fed. Cir. 1998). Moreover, a definition that is provided in the prosecution history also shapes the claim scope. *Loctite Corporation v. Ultraseal Ltd.*, 228 U.S.P.Q. 90, 93-94 (cited with approval in *Renishaw at 1121, n. 3*).

The present claims 79-82 call for "wherein the administered fluid is in the form of a mist." In an Amendment filed July 9, 2001, Appellant sought to overcome the rejection of the claims for anticipation over the disclosure of Embleton by pointing out that the claims call for administration of fluid in the form of a mist. In contrast, Embleton discloses a jet or stream of droplets.

With this Amendment, Appellant provided page 1231 of the Random House Dictionary of the English Language (1987), which defined "mist" as:

1. a cloudlike aggregation of minute globules of water suspended in the atmosphere at or near the earth's surface, reducing visibility to a lesser degree than fog.
2. a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief. . .* (emphasis in the original)

In the following Office Action, mailed on August 14, 2001, the Examiner countered Appellant's definition of mist with the following statement.

Applicant further argues that Embleton's teaching of a jet or a stream of droplets is distinct from a mist. It is noted that page 6, line 10 of the specification defines mist as dispersed droplets in air. *The examiner does not recognize a distinction between mist, multiplicity of droplets, dispersed droplets in air, stream of droplets, or a cloud-like aggregation of minute globules of water.* (emphasis supplied)

In the Amendment filed January 9, 2002 in response to this Office Action, Appellant provided further evidence that a "mist", as generally used and as defined by Appellant. This evidence was in the form of pages 1027 and 1028 of the same dictionary, which defines the term "jet" as:

1. a stream of a liquid, gas, or small solid particles forcefully shooting forth from a nozzle, orifice, etc.
2. something that issues in such a stream, as water or gas . . .

In the subsequent Office Action mailed on May 1, 2002, the Examiner countered by stating that the dictionary definition provided by Appellant:

is entirely consistent with Embleton's use of the phrase "jet or stream of droplets" for application to the eye. It is clear that there is no distinction between a mist and a "jet or stream of droplets" as used by Embleton.

Appellant submits that the Examiner acted improperly in rejecting Appellant's definition of "mist" as distinct from a jet or a stream of droplets. It is to be noted that the "patentee may be his own lexicographer" cases deal with the situation where a patentee defines a term in a way contrary to its accepted usage. In the present case, however, Appellant has, both in the specification and in the prosecution history, defined the term "mist" in a way that is entirely consistent with its accepted usage and the Examiner is attempting to broaden the term to include forms of liquid which are other than mists. This the Examiner may not do. See, *Sextant Avionique S.A. v. Analog Devices Inc.*, 49 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 1999).

In addition, regarding the Examiner's contention that the term "mist" is consistent with the disclosure of Embleton of a jet or stream of droplets, Appellant submits that this statement is incorrect. The entire disclosure of Embleton relates to their discovery that:

the ocular bioavailability of ophthalmologically active compounds can be further enhanced by delivery to the eye in the form of a jet or stream of droplets. Particularly, we have found that smaller quantities of the same treatment liquid, when delivered in this manner can have the same or an improved pharmacological effect. See Embleton, page 2, lines 31-37.

The advantages of a "jet or stream of droplets" is a major theme of the Embleton reference. See, for example page 3, line 1, to page 4, line 8. For example, Embleton discloses on page 3, lines 6-10, that:

The jet or stream can be directed or targeted at a chosen site in an eye; eg, cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva or palpebral conjunctiva where the active compound can be readily absorbed.

From this statement of Embleton, it is clear that a jet or stream of droplets is distinct from a mist. Equating a mist with a jet or stream of drops is antithetical to the teaching of Embleton. A mist cannot be directed or targeted at a chosen site in an eye.

Appellant submits that it is improper for the Examiner to ignore the distinction made by Embleton et al. of the advantage of a jet or stream of droplets and to reject Appellant's claims, partly on the ground that "there is no distinction between a mist and a 'jet or stream of droplets' as used by Embleton." Appellant further submits that, given the definition of mist provided by Appellant, the claims are patentable over the disclosure of Embleton, either alone or in combination with Laibovitz.

2. The Examiner has improperly combined the Embleton and Laibovitz references. Embleton provides a solution to the problem of providing medication to the eye in too great a volume, which results in wastage of medication and drainage of medication into the systemic circulation with potential side effects. Embleton states that drops are not the solution to this problem because they are inherently too large. Embleton solves the problem by the use of a jet or stream of droplets. See page 2, line 34.

The entire thrust of the Embleton patent application is the use of a jet or stream of droplets. As stated on page 3, lines 1-10:

Accordingly, the present invention provides a dosage form useful in ophthalmic treatment, comprising a jet or stream of droplets of treatment fluid, the jet or each droplet having an ophthalmologically active compound in suspension or solution, normally an aqueous solution. The

jet or stream of droplets can be directed or targeted at a chosen site in an eye; eg, cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva or palpebral conjunctiva where the active compound can be most readily absorbed.

Laibovitz addresses the same problem that Embleton addresses, that is the problem of delivering small quantities of medication fluid to the surface of the eye. Laibovitz discloses an apparatus that can be used to deliver small quantities of fluid to the eye. At column 3, lines 23-24, Laibovitz discloses that:

The size of the drop may be generally the size such as is found in an aerosol or mist . . .

Appellant submits that it is improper to combine the disclosure of Laibovitz, that the drops may be the size of those in a mist, with the disclosure of Embleton, which teaches the importance of a jet or stream of droplets, to modify Embleton so as to replace Embleton's jet or stream with a mist and to apply this as a basis for rejecting the present claims drawn to administration of fluid in the form of a mist. Combining the mist of Laibovitz with the device of Embleton would destroy the advantages obtained by the invention of Embleton. Embleton's teaching away from administration other than by a jet or a stream, such as by a mist, is incompatible with Laibovitz's purported disclosure of a mist.

Accordingly, Appellant submits that the claims 79-82, calling for a mist, are patentable over the combined disclosures of Embleton and Laibovitz.

3. Neither Embleton nor Laibovitz discloses administration in the form of a mist

Embleton is discussed above regarding its teaching of the administration of a liquid in the form of a jet or stream of droplets. The Examiner has cited Laibovitz for its purported teaching of administration in the form of a mist. Appellant submits that the Examiner has erroneously construed the teaching of Laibovitz.

Laibovitz discloses an apparatus for delivering small volumes of fluid to the eye. The apparatus employs gas induction to deliver small and accurate volumes of liquid. See, column 3, lines 63-65. The system utilizes the gas to deliver the liquid in the form of small drops, which drops may be the size such as is found in a mist or aerosol. See, column 3, lines 17-24.

Appellant submits that the Examiner has erroneously construed this teaching of Laibovitz to be that the liquid is administered as a mist.

Actually, Laibovitz is silent as to the form in which the liquid is administered. Laibovitz does not indicate whether the liquid is administered, for example, as a jet or stream of droplets, or as a mist, or in some other form. What Laibovitz discloses that *the size of the droplets* may be such as is found in an aerosol or mist. Such a size is compatible both with a mist and with a jet or stream of droplets. This can be determined from the disclosure of Embleton which states that the droplets in Embleton's jet or stream of droplets may be as low as 20 microns in diameter. See, page 3, line 22. Drops of this size may be present in a mist and may also be those in a jet or stream of droplets.

Thus, it cannot be said that Laibovitz discloses administration in the form of a mist. Accordingly, Appellant submits that the Examiner has failed, by combining the disclosures of

Embleton and Laibovitz, to make a prima facie case of obviousness of claims 79-82 drawn to a mist.

## CONCLUSION

For the reasons discussed above, Appellant submits that the Examiner has improperly rejected the pending claims and requests the Board of Patent Appeals and Interferences to remove these bases of rejections and to find the claims patentable.

## IX. Appendix of Claims Involved in the Appeal

75. A method for moisturizing the eye comprising administering to the surface of the eye less than 3 microliters of an aqueous fluid consisting essentially of water.

76. The method of claim 75 wherein the volume of fluid administered to the eye is less than about 2 microliters.

77. The method of claim 75 wherein the volume of aqueous fluid administered to the eye is from 1 to 2 microliters.

78. The method of claim 75 wherein the average size of the droplets is less than 20 microns in diameter.

79. The method of claim 75 wherein the administered fluid is in the form of a mist.

80. The method of claim 79 wherein the volume of fluid administered to the eye is less than about 2 microliters.

81. The method of claim 79 wherein the volume of aqueous fluid administered to the eye is from 1 to 2 microliters.

82. The method of claim 79 wherein the average size of the droplets is less than 20 microns in diameter.



CONCLUSION

For the foregoing reasons, Appellant submits that the Examiner's rejection of claims 75 to 82 was erroneous and requests that the rejection of the claims be reversed.

Respectfully submitted,

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Attorney for Applicant

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on September 24, 2002.

Dated: Sept 24, 2002

Howard M. Eisenberg